

ATTACHMENT "II"

Facsimile No.: 571-273-8300

IN THE UNITED STATES PATENT AND
TRADEMARK OFFICE

RECEIVED
GENERAL INVESTIGATIVE
DIVISION
FEB 21 2006

Application Number: 09/582,809
Filed: June 30, 2000

Applicants: George E. Seidel, Lisa Herickhoff, John Schenk
Title: Sex Specific Insemination of Mammals With Low Number
of Sperm Cells

TC/A.U.: 1634
Examiner: Carla J. Myers

Assignee: XY, Inc. and Colorado State University Research
Foundation

Attorney Docket: XY-Lodo-USNP
Customer No.: 33549

AFFIDAVIT UNDER 37 C.F.R. § 1.132

UNITED STATES OF AMERICA)
STATE OF COLORADO)ss.
COUNTY OF LARIMER)

I, John Schenk, duly sworn and under oath, declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true.

Since approximately 1981, I have been involved to varying degrees in the field of sexing spermatozoa and producing animals from such spermatozoa. This has included at least work with the Texas A&M University, Colorado State University, Ankony Shadow Isle, and ABS Global, Inc. Currently, I am employed by XY, Inc., an assignee the above-captioned patent application. I am an inventor listed on several patents or patent applications in the field of sexing spermatozoa and producing animals from such spermatozoa, including at least: US Patent Application No. 60/400,486 entitled "Sperm Cell Process Systems"; US Patent Application No. 60/400,971 entitled "Low Pressure Sperm Separation System Using Heterospermic Insemination To Assess Sperm Function"; US Patent Application No. 09/001,394 entitled "Sheath Fluids and Collection Systems for Sex-Specific Cytometer Sorting of Sperm"; US Patent Application No.

09/015,454 entitled "System for Improving Yield of Sexed Embryos in Mammals"; US Patent Application No. 09/448,643 entitled "Multiple Sexed Embryo Production System for Mammals"; US Patent Application No. 09/478,299 entitled "Method of Cryopreserving Selected Sperm Cells"; US Patent Application No. 09/582,809 entitled "Sex Specific Insemination of Mammals With Low Number of Sperm Cells"; US Patent Application No. 10/081,955 entitled "Multiple Sexed Embryo Production System for Mammals Using Low Numbers of Spermatozoa"; International Patent Application No. PCT/US03/24,460 entitled "Low Pressure Sperm Cell Separation System"; and International Patent Application No. PCT/US00/30,146 entitled "Methods for Improving Sheath Fluids and Collection Systems for Sex-Specific Cytometer Sorting of Sperm". My duties as Reproductive Physiologist for XY, Inc. require me to review various publications and efforts by others relevant to the field of sexing spermatozoa and producing animals from such spermatozoa and require that I have a certain level of technical expertise in these fields.

By virtue of the foregoing, I have knowledge and skill that is at least representative of those skilled in the art pertaining to sexing spermatozoa and producing animals from such spermatozoa.

I am aware of and have reviewed the specification of the above-captioned patent application. Pages 6-7, 10-16, and 21-22 of the specification of this patent application as filed are attached to this affidavit as Exhibit "A". I also am aware of the claims of the above-captioned patent application as currently amended. These claims are attached to this affidavit as Exhibit "B".

Based on my review of Exhibit "A" and Exhibit "B", I am of the opinion that the claims as currently amended reciting the steps of "separating nonhuman sperm cells based upon said sex characteristic and a rate of at least 1200 separations per second" and "establishing an insemination sample capable of fertilizing at least one egg within said female of said nonhuman species of said mammal at success levels selected from the group consisting of at least 35%, at least 41%, at least 50%, and at least 90% of a typical unsorted insemination dosage and having a number of separated nonhuman sperm cells less than about one-half the number of sperm cells of said typical unsorted insemination dosage" are to be considered an unexpected result of the current invention with respect to the prior art. More particularly, I am not aware of and do not believe the prior art has disclosed achieving such success levels at such separation rates prior to the current invention. In addition, I believe a person of ordinary skill in the art pertaining to sexing spermatozoa and producing animals from such spermatozoa would not have had a reasonable expectation of success of achieving such success levels at such separation rates relying only on the teachings of the prior art.

Moreover, I am of the opinion that the specification teaches the methods and apparatus necessary to enable a person of ordinary skill in the art pertaining to sexing spermatozoa and producing animals from such spermatozoa to accomplish the separation rates and

success levels recited in the claims. The specification at page 10, lines 8-27 discusses a relevant high speed operation of a flow cytometer. The specification at page 11, lines 1-14 discusses that such high speed operation of a flow cytometer may produce stresses on sperm cells that may adversely affect their performance. The specification at page 11, lines 15-16 clearly states that the current invention teaches techniques that may minimize such stresses which sperm cells may experience. A person of ordinary skill in the art reading these passages would understand that while higher separating speeds may be desirable to separate more sperm per given time period in order to produce larger sperm samples within such time period, nevertheless such high speed separating may tend to compromise fertilization success levels due to adverse stress effects on separated sperm cells, and therefore minimizing such adverse stress effects may aid in increasing fertilization success levels.

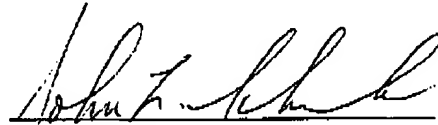
The specification exemplifies a number of techniques that may contribute to minimizing such adverse stress effects. The specification from page 12, line 9 to page 14, line 9 teaches how chemically coordinating a sheath fluid to present minimal changes may reduce the potential stresses that sperm cells experience due to different chemical factor environments in conventional sorting processes, and provides practical examples for at least two sheath fluid compositions. The specification from page 14, line 21 to page 16, line 2 teaches how the configuration and positioning of a collection container may be selected to minimize the potential physical damage to separated sperm cells that may attend conventional collection techniques. The specification from page 16, line 3 to page 16, line 26 teaches how a collector fluid may be selected to minimize potential stresses created by perhaps unbalanced nutrient levels in conventional sorting processes. The specification from page 21, line 23 to page 22, line 3 teaches that insemination deep within a uterine horn may contribute to achieving better results for successful fertilization levels as compared to conventional insemination techniques, which may be understood to aid in counteracting the potential impairment of sperm cells subjected to the stresses of high speed separating.

Perhaps importantly, the mere recognition of the stress aspects of high speed separating, and that steps to counteract such stress aspects may increase fertilization success levels for sperm separated at such high rates, may be considered a teaching of the present invention not taught in the prior art. Accordingly, the selection of any particular stress minimization technique, including those inventive techniques taught by the current invention, may be accomplished by ordinary skill in the art once the stress aspect and the significance of counteracting such stresses are recognized as being important. Moreover, the specification makes these points clearly understandable to one of ordinary skill in the art at page 7, lines 17-19, where it is stated that the techniques are disclosed in a general fashion so that they may be applied to specific systems and applications once the general principles are understood, and at page 6, lines 6-9, where it is stated that various techniques and substances are represented, but various combinations and permutations can be used in a manner which may be optimized for performance based on species,

separation techniques, goals, and other parameters involved in a specific processing application.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.


DATED this 20 day of February, 2006.


John Schenk

UNITED STATES OF AMERICA)
STATE OF COLORADO)ss.
COUNTY OF LARIMER)

SUBSCRIBED AND SWORN to before me in the County of Larimer, State of Colorado, United States of America, by John Schenk this ____ day of February, 2006. WITNESS my hand and official seal pursuant to the authority vested in me as a Notary Public by the State of Colorado.




Notary Public
My Commission Expires: 7/18/2009